CASE AUTH/3722/1/23 ***NO BREACH OF THE CODE***

COMPLAINANT v OTSUKA

Allegations about market research

CASE SUMMARY

This case was in relation to market research commissioned by Otsuka Europe Ltd and Lundbeck A/S (Lundbeck Global) that took place annually between 2018 and 2021. The case in relation to Lundbeck was proceeded with under Case AUTH/3723/1/23.

The complainant's allegations concerned the content of the market research, which they alleged had a promotional purpose, and to Otsuka's review and approval process for the market research.

There was an appeal by Otsuka of four of the Panel's rulings.

The outcome was:

No Breach of Clause 9.1 (2016 Code) [Panel's breach ruling overturned at appeal]	**Requirement that high standards must be maintained at all times**
No Breach of Clause 12.2 (2016 Code)	**Requirement that market research activities must not be disguised promotion**
No Breach of Clause 9.1 (2019 Code) (x2) [Panel's breach ruling overturned at appeal]	**Requirement that high standards must be maintained at all times**
No Breach of Clause 12.2 (2019 Code) (x2)	**Requirement that market research activities must not be disguised promotion**
No Breach of Clause 5.1 (2021 Code) [Panel's breach ruling overturned at appeal]	**Requirement that high standards must be maintained at all times**
No Breach of Clause 25.4 (2021 Code)	**Requirement that market research activities must not be disguised promotion**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from an anonymous, contactable complainant about market research commissioned by Otsuka Europe Ltd and Lundbeck A/S (Lundbeck Global). The case in relation to Lundbeck Limited was proceeded with under Case AUTH/3723/1/23. The complainant stated that they were representing a group of employees and former employees of Otsuka EU and Lundbeck.

COMPLAINT

The complainant stated:

> '*I would like to point out that from 2018 until this year* [2022]*, repetitive and similar market research* [(MR)] *has been manaide* [sic] *by Otsuka Europe Ltd and then carried out in the various EU countries. It has been brought to the attention of Otsuka Europe Ltd on many occasions that in the market research questionnaire was repeatedly naming the product brand name (Abilify Maintena) and that this was obviously an activity* [with] *promotional purposes. Furthermore, in the questionnaires, each year, they asked to the HCP* [(health professional)] *basically to transcribe data from the patient's clinical records in the MR's patient form, diagnosis, treatment, management, reactions, efficacy, etc... many times it has been reported by colleagues of the medical departments that they seemed Clinical study's question instead of MRs questions. Moreover, the internal procedure of Otsuka Europe Ltd does not provide for any filter by European compliance, on the European minimum requirements for MRs materials and questionnaire, EU Compliance review the purpose or the design of the MR, but they do not review the questionnaire* [and] *several time the comments received from affiliate on compliance topics are not considered and Otsuka Ltd do not apply any change. Please find below an example, that is a part of one of the questionnaires of these years, in 2022 the questions were slightly modified in grammatical terms but the meaning is the same. Trying to hide the real purpose, the investigation of patient clinical records and HCPs prescription habits they arrived at absurd questions such as "please* [now] *think of the last 3 hypothetical patients you have seen in the last month".*'

The complainant provided the following example:

> '*Patient Record Form section. For statistical reasons, it is important that you think not about the patients you might consider most interesting or significant, but EXACTLY THE LAST 3 PATIENTS YOU VISITED. Now concentrate and look at the patient records of the last 3 schizophrenia patients you personally saw who are treated with atypical LAI antipsychotics. Enter the patient's year of birth: _____ When were you diagnosed with schizophrenia? Select the month and year. _____ _____ (month) (year) Which symptoms of schizophrenia are predominant for this patient? How many schizophrenia-related relapses has this patient experienced? What is this patient's level of functioning? Which healthcare facility referred this patient to your attention? What atypical LAIs is the patient taking? 1. monthly aripiprazole 2. olanzapine pamoate extended release 3. risperidone LAI 4. monthly paliperidone palmitate 5. Paliperidone palmitate administered quarterly. In which healthcare facility was the patient initiated? When did the patient start taking the current atypical LAI antipsychotic (<Scripter:*

Placeholder for current drug name>)? Select the month and year. _____ _____ (month) (year) Patient received a different antipsychotic (oral or injectable) prior to current atypical LAI antipsychotic. What antipsychotic did the patient receive prior to the current atypical LAI antipsychotic? List of LAI and oral antipsychotics follows. Overall, how many different types of LAI antipsychotics (typical or atypical) has this patient received over time? Which of the following best describes what happened during your last visit to this patient? Now complete the patient record form of the second patient of the last 3 suffering from schizophrenia that you see personally and who are receiving atypical LAI antipsychotics. Now complete the patient record form of the third patient of the last 3 suffering from schizophrenia that you see personally and who are receiving atypical LAI antipsychotics.'

FURTHER INFORMATION FROM THE COMPLAINANT

The complainant stated that Otsuka Europe Ltd was the marketing authorisation holder of Abilify Maintena and the EU Otsuka headquarters, this meant that they would be legally and ethically responsible for EU affiliates and for the co-promoter companies.

The complainant stated that, in this case, Otsuka Europe Ltd and Lundbeck were contract owners for the market research. They selected and engaged the market research agency that managed the market research and the review, approval and distribution of the material in the European countries, including the UK.

The complainant stated that the agency interviewed at least 100 UK health professionals each year from 2017 to 2022 and 100 more health professionals from each other country (Spain, Germany, Italy and so on). Each year, the same questionnaire was used (repetitive market research) and every time they asked the health professional to transcribe the clinical data of the last three patients they saw into a specific patient record form. In some cases, the health professional was asked to think about the last three virtual or hypothetical patients they saw and to transcribe the clinical data into this virtual patient data form. The complainant alleged that the clinical data of the patient would be used just in a clinical study and not in market research.

The complainant stated that Otsuka Europe should have the certification of all the materials and should be able to review and check UK and EU requirements.

When writing to Otsuka, the PMCPA asked it to consider the requirements of Clauses 12.2 and 9.1 of the 2016 and 2019 Codes and Clauses 5.1 and 25.4 of the 2021 Code.

OTSUKA'S RESPONSE

Otsuka Europe noted that the PMCPA had received a complaint from an anonymous contactable complainant regarding market research activities conducted by Otsuka Europe and Lundbeck. Lundbeck UK would be submitting a separate response to the complaint.

Otsuka Europe stated that the market research referred to by the complainant appeared to be the Abilify Maintena Awareness, Trial, and Usage (ATU) tracking market research, which was conducted once each year between 2018 and 2021 (referred to as waves 1 to 4). The market research was conducted by a market research agency on behalf of both Otsuka Pharmaceutical Europe Ltd and H. Lundbeck A/S (Lundbeck Global) with psychiatrists from the United Kingdom,

Germany, France, Spain, Italy, Australia in all four years and Canada between 2018 and 2020 (waves 1 to 3). The objective of this market research was to track the development of Abilify Maintena in the market of atypical long-acting injectable (aLAI) antipsychotics, in order to be able to fine-tune marketing activities.

Otsuka Europe stated that the format of this market research was an online questionnaire. Copies of the screener and questionnaire for each wave were provided. There were several different versions of the screener and questionnaire used during the fieldwork for each wave. This was primarily due to adapting the screener to achieve a sufficient sample size. Over the four waves the following methods of recruitment were used during the market research:

- Panel-matched recruitment from a market research panel
- Free-found recruitment from a market research panel
- Recruitment directly from a target list of psychiatrists.

The target list comprised psychiatrists visited by the respective companies in relation to Abilify Maintena within a specified time period, e.g. within the last 12 months. For the panel-matched recruitment, the market research agency's fieldwork partner matched psychiatrists on the target list against their panel of health professionals. The individuals taking part in the market research remained anonymous to Otsuka and Lundbeck regardless of the recruitment methodology. The objective of using the target list or panel matching was to be able to track whether Otsuka Europe's marketing activities showed an effect in the results of the ATU tracking market research.

Otsuka Europe stated that the sample sizes per wave ranged from 60 to 103 per country. This was quantitative market research and the sample sizes needed to be sufficient to be able to perform subgroup analysis of the data. However, these sample sizes represented a small percentage of the total number of psychiatrists in each country.

Otsuka Europe submitted the aggregated reports for all four waves of the market research contained details of the specific methodology used in that wave, sample sizes for each country, and the subgroup analyses performed. Separate country reports were also produced for each wave of the market research to be able to inform activities at an individual country level.

Otsuka Europe submitted that the complainant appeared to have three allegations relating to this market research:

1. The market research was an activity with a promotional purpose
2. The use of patient record forms in the market research constituted a clinical study
3. The market research materials were not reviewed by Otsuka Europe Compliance

Otsuka Europe responded to these allegations below.

Allegation about the market research having a promotional purpose

Otsuka stated that the complainant alleged that the market research repeatedly named the brand name (Abilify Maintena), and this meant that the activity was conducted with a promotional propose. Otsuka Europe submitted that to meet the objective of the market research, as stated above, it was necessary to refer to the brand and non-proprietary names of Abilify Maintena in the questionnaire. The use of these names was not excessive and, where

mentioned, this was done alongside competitors. Furthermore, these names were randomised within the questionnaire so that there was no emphasis on or bias towards Abilify Maintena. The instruction to randomise the names was documented in the programming notes of the screener and questionnaire. Otsuka Europe submitted that the use of the brand name was in accordance with section 5.2 of the BHBIA (British Healthcare Business Intelligence Association) Legal and Ethical Guidelines for Healthcare Market Research, which stated:

> 'You must avoid brand names as much as possible. Using them unnecessarily or repeatedly could make your MR [market research] look like promotion. Use 'Product X' unless:
>
> − reaction to the name or its visual representation is an objective
>
> − using a name is essential to the interpretation of the stimulus, and this is in turn essential to the study objectives
>
> − you need to refer to a specific product e.g. in brand tracking. If possible compare with other brands to reduce the product's standout and so reduce the risk of the MR being considered promotion.'

Otsuka Europe stated that the complainant also alleged that the market research was repetitive and similar. Otsuka Europe submitted that, to meet the objective of the market research, it was necessary to repeat the market research to monitor the uptake of Abilify Maintena within the aLAI antipsychotic class and track the relative importance of treatment characteristics for aLAI prescribing across this class over time. Otsuka Europe submitted that the period between waves of the market research starting each year was approximately 12 months, during which time there could be significant changes in market dynamics that Otsuka needed to be aware of in order to inform its activities.

With the above in mind, Otsuka Europe submitted that it considered that the market research at issue was conducted for a legitimate business purpose, was not promotional or disguised in that regard and was consistent with the high standards expected of pharmaceutical company activities. Otsuka Europe therefore denied breaches of Clauses 25.4 and 5.1 of the 2021 Code and Clauses 12.2 and 9.1 of the 2016 and 2019 Codes.

Allegation about the market research as a means of investigating patient clinical records

Otsuka Europe stated that, as part of the market research questionnaire, respondents were asked to complete three patient record forms, based on the last three patients with schizophrenia they had seen and who received treatment with aLAI antipsychotics. Otsuka Europe submitted that this patient data presented in the reports was anonymised and aggregated and allowed it to track treatment dynamics (e.g. switch, re-start, dosage adjustment, etc.) across the aLAI class in a robust dataset upon which to base any adjustment to its marketing activities. Otsuka Europe stated that the complainant alleged that this aspect of the market research constituted clinical research.

Otsuka Europe submitted that Section 1.3 of the European Pharmaceutical Market Research Association (EPHMRA) Code of Conduct 2022 provided a clear differentiation between market research and non-interventional studies:

> ‘Market Research is carried out for a commercial purpose i.e. to investigate market behaviour and opportunities to inform business decision making, clinical endpoints are not needed for Market Research.’

Whereas:

> ‘Non-interventional research is carried out for a clinical purpose i.e. to assess safety, efficacy or tolerability, its ultimate purposes are to advance science, the treatment of disease, and improve patient outcomes.’

The EPHMRA Code of Conduct 2022 further stated:

> ‘Even Market Research that involves the collection of anonymised patient data detailing conditions, symptoms and treatments this does not mean it is non-interventional research. Market Research using anonymised patient record data is analysed in aggregated form to generate information upon market patterns.’

Otsuka Europe submitted that this part of the market research was aligned with the overall objective of the market research, which was to investigate market behaviour and to inform business decision making, and therefore clearly fitted into the category of market research, rather than clinical research as claimed by the complainant. Otsuka Europe therefore denied breaches of Clause 5.1 of the 2021 Code and Clause 9.1 of the 2016 and 2019 Codes.

Allegation about the market research materials not being reviewed by Otsuka Europe Compliance

Otsuka Europe stated that the complainant alleged that the screener and questionnaire were not reviewed by the European Compliance team. This was correct; as per Otsuka Europe processes there was no requirement for the screener and questionnaire to be reviewed by Otsuka Europe Ethics and Compliance. Otsuka Europe submitted that there was no Code requirement that market research materials were reviewed by members of a compliance team.

Otsuka Europe submitted that this material was examined by a signatory at Otsuka Europe to ensure that it complied with the Code. Copies of the different versions of screener and questionnaire approved by Otsuka Europe were provided to the Panel. Otsuka Europe stated that minor changes to materials post this approval were agreed between the market research agency and the two companies over email.

Otsuka Europe stated that the complainant also alleged that compliance concerns from Otsuka affiliates were not considered by Otsuka Europe. Otsuka Europe noted that the complainant had not provided any evidence to substantiate this. During Otsuka Europe’s investigation into this matter, Otsuka Europe was unable to find evidence that feedback from affiliates on this market research was not addressed.

Otsuka Europe denied breaches of Clause 5.1 of the 2021 Code and Clause 9.1 of the 2016 and 2019 Codes.

FURTHER RESPONSE FROM OTSUKA

After giving preliminary consideration to the case, the Panel asked Otsuka to confirm which materials the comment in Otsuka's original submission 'minor changes to materials … were agreed between the market research agency and the two companies over email' after the material had been 'examined by a signatory at OPEL to ensure that it complied with the ABPI Code of Practice' related to, having noted that Otsuka had admitted that the market research for each wave had potentially not been examined as required by Clause 8.3 and its supplementary information.

Otsuka noted that the specific allegation by the complainant related to this point in Case AUTH/3722/1/23 was *'the internal procedure of Otsuka Europe Ltd does not provide for any filter by European compliance, on the European minimum requirements for MRs materials and questionnaire, EU Compliance review the purpose or the design of the MR, but they do not review the questionnaire ad* [sic] *several time the comments received from affiliate on compliance topics are not considered and Otsuka Ltd do not apply any change'*. Therefore, Otsuka stated, there was no allegation by the complainant that the material was not examined as required by the Code.

Otsuka submitted it is an established principle under the Code that the Panel can only consider the matters alleged by the complainant. For example, Case AUTH/2473/1/12 stated 'The Constitution and Procedure did not permit the Panel to consider matters which were not the subject of a complaint or voluntary admission and thus it could not rule on this matter.' Otsuka stated that, for clarity, it did not consider that it made a voluntary admission in its response to Case AUTH/3722/1/23.

Otsuka noted the Panel's email stated that market research had potentially not been examined as required by the supplementary information to Clause 8.3 of the 2021 Code however, Otsuka submitted, the Case Preparation Manager did not ask Otsuka to respond in relation to this clause, nor the equivalent clause in the 2016 and 2019 Codes. Whilst the supplementary information to Clause 25.4 of the 2021 and Clause 12.2 of the 2016 and 2019 Codes stated that market research should be examined, Otsuka submitted that it responded to this clause in relation to the allegation by the complainant that the market research had a promotional purpose.

Based on the above, it was not clear to Otsuka why this information was necessary for the Panel to make its ruling and Otsuka requested clarification from the PMCPA as to why this information was being requested.

PANEL RULING

The Panel noted that Otsuka Europe was the marketing authorisation holder for Abilify Maintena (aripiprazole), an atypical long acting injectable (aLAI) antipsychotic, which was supplied in the UK by Otsuka UK and Lundbeck under a co-promotion agreement. There were several formulations of aripiprazole available in the UK, most of which were in tablet form and were available from several companies; Abilify Maintena was the only injectable form of aripiprazole available in the UK.

The Panel noted that the complainant alleged that market research by Otsuka Europe Ltd and Lundbeck was repetitive and promotional in nature. The complainant alleged that the market

research questionnaire repeatedly mentioned the product brand name (Abilify Maintena) and that the questions seemed more like clinical study questions than market research questions.

The Panel noted that the market research, which was an online questionnaire, had been undertaken in a number of countries, including the UK. The Panel noted that the use of the market research in the UK was not unacceptable, providing it complied with the requirements of the Code. Clause 25.4 of the 2021 Code (Clause 12.2 of the 2016 and 2019 Codes) stated that market research activities, clinical assessments, post-marketing surveillance and experience programmes, post-authorisation studies (including those that were retrospective in nature) and the like must not be disguised promotion. They must be conducted with a primarily scientific or educational purpose. The supplementary information referred to the Legal and Ethical Guidelines for Healthcare Market Research produced by the British Healthcare Business Intelligence Association (BHBIA). It also stated that market research must be unbiased and non-promotional and that market research material should be examined to ensure that it does not contravene the Code.

The Panel noted Otsuka Europe's submission that the objective of this market research was to track the development of Abilify Maintena in the market of aLAI antipsychotics, in order to be able to fine-tune marketing activities.

The Panel noted that the market research was conducted once each year between 2018 and 2021 (referred to as waves 1 to 4); copies of the screener and questionnaire were provided by Otsuka for each wave.

In relation to the complainant's allegation that the series of questionnaires was repetitive, the Panel noted Otsuka Europe's submission that, to meet the objective of the market research, it was necessary to repeat the market research to monitor the uptake of Abilify Maintena within the aLAI antipsychotic class and track the relative importance of treatment characteristics for aLAI prescribing across this class over time.

In relation to the complainant's allegation that the market research was promotional and repeatedly mentioned the product brand name, the Panel noted Otsuka's submission that it was necessary to refer to the brand name and non-proprietary name in the questionnaire but that the use of the names was not excessive, was always done alongside competitors and the order of the names was randomised. The Panel examined the template market research questionnaire for each wave and noted that where Abilify Maintena was mentioned by name, this was followed by a list of other products and it appeared that on each occasion the scripter was directed to randomise the list order for each participant. The Panel also noted that where Abilify Maintena was one of the products mentioned by name identification of the products by brand appeared to be necessary to the question.

In relation to the complainant's allegation that the questions seemed more like clinical study questions than market research, the Panel noted Otsuka Europe's submission that the patient data presented in the reports was anonymised and aggregated and allowed it to track treatment dynamics across the aLAI antipsychotic class in a robust dataset upon which to base any adjustment to its marketing activities. In this regard, the Panel noted that the questionnaire asked the participant to provide information about the last three adult patients diagnosed with schizophrenia the participant had seen who had received an aLAI antipsychotic as the primary treatment for schizophrenia (not the last three hypothetical patients, as alleged by the complainant). The questionnaire also stated that the patient must not be participating in any

clinical trials; and that participants should have the actual patient records at hand when completing this section of the market research. Instructions to the participant made it clear that patient identifiable information should not be given.

The Panel noted the distinction between market research and non-interventional study research made by the European Pharmaceutical Market Research Association (EPHMRA), as cited by Otsuka in its response. The Panel noted Otsuka's submission that the objective of the market research was 'to investigate market behaviour and to inform business decision making' and that the patient data was 'anonymised and aggregated'. The Panel considered that neither the questionnaires nor the outcome reports went beyond the stated business objectives of the market research.

The Panel considered that the overall objective of the market research, as stated by Otsuka and evidenced in the questionnaires and outcome reports provided, appeared to address a legitimate business matter. The Panel considered that it was not unreasonable for a pharmaceutical company to conduct market research to monitor and track the position of a particular medicine within a class and to gain an understanding of the factors affecting prescribing, provided it met the requirements of the Code.

The Panel, noting all of its comments above, did not consider that either the content of the market research questionnaires or the way in which the market research was conducted was promotional for the reasons alleged by the complainant. The Panel accordingly ruled **no breaches of Clause 12.2 of the 2016 Code (Wave 1), Clause 12.2 of the 2019 Code (Waves 2 and 3) and Clause 25.4 of the 2021 Code (Wave 4)**.

The Panel noted the complainant's allegation that 'the internal procedure of Otsuka Europe Ltd does not provide for any filter by European compliance, on the European minimum requirements for market research materials and questionnaire, EU Compliance review the purpose or the design of the market research, but they do not review the questionnaire'. The Panel noted the broad nature of the allegation which appeared to refer to the review and approval process.

The Panel noted Otsuka Europe's submission that the allegation that the screener and questionnaire were not reviewed by the European Compliance team was correct; its policies did not require these materials to be reviewed by Otsuka Europe Ethics and Compliance. Otsuka Europe submitted that there was no Code requirement that market research materials were reviewed by members of a compliance team but that the material was examined by a signatory at Otsuka Europe to ensure that it complied with the Code.

The Panel noted that Clause 8.3 of the 2021 Code (Clause 14.3 of the 2016 and 2019 Codes) did not require that market research materials were certified. The relevant Supplementary Information (Examination of Other Material), and the Supplementary Information to Clause 25.4 of the 2021 Code (Clause 12.2 of the 2016 and 2019 Codes) (Market Research), provided that they should be examined to ensure they did not contravene the Code or the relevant statutory requirements. The Panel noted that these clauses had not been cited by the Case Preparation Manager and therefore considered the broad allegation relating to review and approval under Clause 5.1 of the 2021 Code (Clause 9.1 of the 2016 and 2019 Codes).

The Panel noted that Lundbeck and Otsuka had submitted separate and distinct responses to the complaint and the Panel had to consider the evidence in relation to each case separately.

The two responses were not entirely consistent. The Panel noted this was a co-promotion arrangement whereby the companies would be jointly responsible for the activity and materials, the questionnaire etc. The companies had not made any detailed submissions about the examination arrangements, whether each company examined market research material separately or whether there were joint arrangements with one signatory. However, the Panel noted that it had to consider the matter in relation to the allegations raised and the evidence before it in each separate case.

The Panel noted that, while copies of the job bag certificates had been provided, Otsuka's submission stated that 'minor changes to materials' had been 'agreed between the market research agency and the two companies over email' after approval. The Panel had not been provided with any additional information regarding these 'minor changes'. It was not clear to which materials changes had been made, or who had made and/or communicated the changes. The Panel noted Otsuka's response to its query in this regard did not provide further clarity on this matter. The Panel noted that Otsuka made the comment about changes being made to materials within the context of its comments about approval of the material at issue; the Panel considered that this potentially applied to each wave of the market research material. The Panel noted Otsuka's submission that it had not intended to make a voluntary admission on this point. The Panel however had not treated Otsuka's comments on this point as a voluntary admission about a new matter, it rather considered that its comments were an integral part of Otsuka's response to the very broad allegation about the approval process which, given the nature of the material at issue, related to examination. The Panel noted its comments above that this matter would be considered in relation to the requirements for high standards.

The Panel noted Otsuka's statement and considered that the market research material for each wave had potentially not been examined as set out in the supplementary information to Clause 8.3. The Panel considered that, while the examination of material to ensure that it did not contravene the Code or the relevant statutory requirements did not require a certificate, it was clear that a signatory or an appropriately qualified person (AQP) was required to examine the version of the material that was ultimately used. The Panel noted the requirements of Clauses 5.1 and 5.2 of the Code, which recognised the 'special nature of medicines' and required that 'high standards must be maintained at all times'. The Panel queried how high standards could be assured if the examination of materials was not carried out on the final form of the material, as changes made after examination could render the material inconsistent with the Code. The Panel considered that a robust approval system underpinned self-regulation. The Panel noted that the complainant bore the burden of proof but considered that, given the clear submission by Otsuka in relation to the market research materials, high standards had not been maintained in relation to their approval. The Panel therefore ruled **breaches of Clause 9.1 of the 2016 Code (wave 1), Clause 9.1 of the 2019 Code (wave 2), Clause 9.1 of the 2019 Code (wave 3) and Clause 5.1 of the 2021 Code (wave 4)**.

* * * * *

During its consideration of this case the Panel noted with concern the differences between the responses of Lundbeck and Otsuka in relation to the examination of the final form of materials.

APPEAL BY OTSUKA

Otsuka's appeal is reproduced below.

> 'Otsuka Pharmaceutical Europe Ltd (OPEL) is appealing the Panel's ruling of breaches of Clause 9.1 of the 2016 Code (wave 1), Clause 9.1 of the 2019 Code (wave 2), Clause 9.1 of the 2019 Code (wave 3) and Clause 5.1 of the 2021 Code (wave 4) for the reasons set out below:
>
> ***1. The rulings are on a matter outside the scope of the complaint***
>
> The Panel's ruling of a breach of Clauses 5.1 (2021 Code) and 9.1 (2019 & 2016 Codes) for the market research was based on the Panel's consideration that OPEL had failed to examine the market research material at issue in accordance with the requirements of Clause 8.3.
>
> We disagree with the Panel's interpretation that the complainant's allegation about the OPEL approval process was broad in nature; it was in fact limited to an assertion that the Compliance team at OPEL did not approve market research. There was no allegation that market research was not approved at all.
>
> In its ruling, the Panel have interpreted the complaint to be about the entire approval process and extrapolated that in order to consider the matter in relation to the requirements of Clause 8.3 of the Code, specifically that companies examine market research material in order to ensure that it complies with the Code.
>
> This clause and this matter did not form part of the complaint and were not raised by the Case Preparation Manager. Therefore, OPEL did not provide a response in that regard.
>
> During the Panel's consideration of the complaint, we received an email on 28 February 2024 from the PMCPA, with a query from the Panel in relation to the comments in our response to the complaint that *"Minor changes to materials post this approval were agreed between the market research agency and the two companies over email"*. In this email, the PMCPA raised the requirements of Clause 8.3 and its supplementary information. We, quite reasonably, questioned why this clause had been referred to but received no response. On receipt of the Panel ruling, we noted that it was stated that our response to the query *"did not provide further clarity on this matter"*. Our query as to whether the question was in fact outside the scope of the complaint was, it seems, ignored.
>
> It is an established principle under the Code that the Panel can only consider the matters alleged by the complainant. For example, Case AUTH/2473/1/12 states *"The Constitution and Procedure did not permit the Panel to consider matters which were not the subject of a complaint or voluntary admission and thus it could not rule on this matter"*. The Panel's ruling in this case is an abuse of this principle and relates to a matter outside the scope of the complaint.

2. Reference in the Panel ruling to examination of "final form"

The basis for the Panel's ruling of a breach of Clauses 5.1 (2021 Code) and 9.1 (2019 & 2016 Codes) was that the *"examination of materials was not carried out on the **final form** of the material"* [emphasis added], not that the content of the material changed following examination; these are two very different matters.

There is no requirement in the Code, including in Clause 8.3 and its supplementary information, to examine the final form of material. If this ruling went unchallenged it would indicate that the Panel expects companies to examine material in the ***exact form in which it will be used***, including examining printed materials should the intention be that they are used in hard copy. This is not a current requirement of the Code and the ruling has significant implications for all companies, not just OPEL. For example, examining this market research material in the 'exact form which it will be used' would involve verifying over 40 pages of programmed text in English, French, German, Italian and Spanish, including verifying programming code validation for every question, checking all question routing possibilities (dependent on respondent's previous answer) as well as confirming randomisation of answers across multiple questions.

When we questioned reference in the Panel's ruling to "final form" the response in the PMCPA's letter dated 21 March 2024 **[copy provided to the complainant following an appeal being lodged – an extract is reproduced below]** demonstrated a lack of understanding of the Code requirements relating to certification and examination. The Appeal Board will no doubt have a copy of the full response, but a key comment was:

"*It might be helpful to refer to the Supplementary Information to Clauses 8.1 and 8.2, Appropriately Qualified Persons, which expressly refers to the examination and signature of the final form of printed material which has been certified electronically as set out in the supplementary information to Clause 8.1. The phrase 'final form' is therefore used in the Code in relation to both examination and certification*"

The wording in the supplementary information to Clauses 8.1 and 8.2, Appropriately Qualified Persons quoted in the PMCPA's response relates to the supplementary information to Clause 8.1, Certification which, as the title suggests, relates to certification only (rather than certification and examination) and states:

When certifying material where the final form is to be printed, companies can certify the final electronic version of the item to which no subsequent amendments will be made. When such material is printed, the company must ensure that the printed material cannot be used until the item has been examined and signed in its final form to ensure it accurately reflects the content and presentation certified electronically. In such circumstances, the material will have a certificate and a declaration approving the final form and both must be preserved as they form the certification of the item. The examination of the printed form can be carried out by a signatory, an appropriately qualified person signatory (AQP signatory) or an appropriately qualified person (AQP).

Therefore, it is clear that this requirement relates to material that needs to be certified under the Code. To those unfamiliar with the Code, the supplementary information to Clauses 8.1 and 8.2 could be confusing in its use of the term "examine" when referencing the requirement to "examine and sign" the final form of printed material which has been certified electronically, but it is worrying that this confusion extends to those at the very authority expected to administer the Code.

To further reinforce that the approval of "final form" relates to certification only, we refer to material produced by the PMCPA to support the implementation of the 2021 Code. At the time, the PMCPA conducted webinars to help companies understand the new Code; slide 29 of the summary slides distributed by the PMCPA after one of these webinars contains a table which demonstrates that examination of the final form applies only to material that is electronically certified first. Furthermore, the wording is not the same in the equivalent clauses of the 2019 and 2016 Codes, as there is no reference to examining the final form of printed material – these versions of the Code refer to the final form being "checked and signed".

3. There are very few requirements in the Code in relation to examination

Further to point 2 above, the Code is relatively silent on the requirements for the process of examination. Clause 8.3 of the 2021 Code requires that examination is conducted by either a signatory or an AQP (appropriately qualified person). Information is provided as to who may be an AQP in the supplementary information to Clauses 8.1 & 8.2 and there is no requirement in the Code that AQPs are notified to the PMCPA or MHRA. Clause 14.3 of the 2019 & 2016 Codes required that material was examined but was silent on who may conduct this examination. In all cases the examination is to "*to ensure that it does not contravene the Code or the relevant statutory requirements*". During the implementation of the 2021 Code, the PMCPA stated that *"It is for companies to decide how Examination is performed…"* (Slide 29 of [the PMCPA slides referred to above])

Whilst some amendments were made to the market research after formal examination by a signatory in Zinc/PromoMats, these were minor amends primarily relating to recruitment of participants and were inconsequential in relation to the objective and content of the market research. These minor amendments were agreed by those very familiar with conducting market research and the requirements thereof and were, therefore, suitably qualified to make those decisions on behalf of Otsuka. Details of these minor changes and who from Otsuka approved these changes are [provided]. Making these minor amends does not appear to be contrary to the requirements of either Clauses 8.3 (2021 Code) or 14.3 (2019 & 2016 Codes).

The main requirement of examination, as noted above, is that the material must not contravene the Code and in this case the Panel "*did not consider that either the content of the market research questionnaires or the way in which the market research was conducted was promotional*". The Panel's ruling, therefore, that making minor amends to market research material after examination was a failure to maintain high standards, does not appear to be based on any requirement in the Code, or indeed the content of the material at issue. We thus question the basis of the ruling altogether.'

EXTRACT FROM PMCPA LETTER OF 21 MARCH TO OTSUKA

'The relevant part of the Panel's ruling is set out below:

The Panel noted Otsuka's statement and considered that the market research material for each wave had potentially not been examined as set out in the supplementary information to Clause 8.3. The Panel considered that, while the examination of material to ensure that it did not contravene the Code or the relevant statutory requirements did not require a certificate, it was clear that a signatory or an appropriately qualified person (AQP) was required to examine the version of the material that was ultimately used. The Panel noted the requirements of Clauses 5.1 and 5.2 of the Code, which recognised the 'special nature of medicines' and required that 'high standards must be maintained at all times'. The Panel queried how high standards could be assured if the examination of materials was not carried out on the final form of the material, as changes made after examination could render the material inconsistent with the Code. The Panel considered that a robust approval system underpinned self-regulation. The Panel noted that the complainant bore the burden of proof but considered that, given the clear submission by Otsuka in relation to the market research materials, high standards had not been maintained in relation to their approval. The Panel therefore ruled breaches of Clause 9.1 of the 2016 Code (wave 1), Clause 9.1 of the 2019 Code (wave 2), Clause 9.1 of the 2019 Code (wave 3) and Clause 5.1 of the 2021 Code (wave 4).

The Code sets out the requirements for 'certification' in Clause 8 and its supplementary information including detailed procedural requirements and a reference to the phrase 'final form'. 'Final form' is a descriptive term and is used to make clear that no further changes should be made to the material. Final form is not a defined term in the Code.

In the Panel's view, examination should be carried out on the final form of the material that is used in order to ensure the material does not contravene the Code or the relevant statutory requirements; in this regard the Panel noted its comment: 'The Panel queried how high standards could be assured if the examination of materials was not carried out on the final form of the material, as changes made after examination could render the material inconsistent with the Code.'

It is important to note that the Code imposes no procedural requirements for examination; it is for companies to adopt a proportionate process and to satisfy themselves that the material that is used has been examined by a signatory or an appropriately qualified person in its final version/form.

It might be helpful to refer to the Supplementary Information to Clauses 8.1 and 8.2, Appropriately Qualified Persons, which expressly refers to the examination and signature of the final form of printed material which has been certified electronically as set out in the supplementary information to Clause 8.1. The phrase 'final form' is therefore used in the Code in relation to both examination and certification.'

RESPONSE FROM THE COMPLAINANT

There was no response from the complainant.

APPEAL BOARD RULING

The Appeal Board had further details about Otsuka's approval of the market research material at issue, which had not been before the Panel.

The Appeal Board took account of Otsuka's clarification that while some changes were made to the material after it had been examined by a signatory in the company's electronic approval system, these were minor changes that were checked by an appropriately qualified person with knowledge of both the Code and the British Healthcare Business Intelligence Association (BHBIA) guidelines, who was familiar with conducting market research. The Appeal Board took account of Otsuka's submission that the amends primarily related to details of the recruitment criteria for participants. All amends had been assessed by an appropriately qualified person as inconsequential in relation to the objective and content of the market research and all amends had been approved by them over email before the material was used.

The Appeal Board considered that the complainant had not established, on the balance of probabilities, that Otsuka had failed to maintain high standards in relation to its approval of the market research material at issue. The Appeal Board ruled no breaches of Clause 9.1 of the 2016 Code (wave 1), Clause 9.1 of the 2019 Code (wave 2), Clause 9.1 of the 2019 Code (wave 3) and Clause 5.1 of the 2021 Code (wave 4). The appeal was successful on all points.

Complaint received **9 December 2022**

Case completed **24 April 2024**